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Original Article

Early vibration assisted physiotherapy in toddlers with cerebral palsy – a randomized controlled pilot trial

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Abstract

Objectives: to investigate feasibility, safety and efficacy of home-based side-alternating whole body vibration (sWBV) to improve motor function in toddlers with cerebral palsy (CP). **Methods:** Randomized controlled trial including 24 toddlers with CP (mean age 19 months (SD±3.1); 13 boys). Intervention: 14 weeks sWBV with ten 9-minute sessions weekly (non-individualized). Group A started with sWBV, followed by 14 weeks without; in group B this order was reversed. Feasibility (≥70% adherence) and adverse events were recorded; efficacy evaluated with the Gross Motor Function Measure (GMFM-66), Pediatric Evaluation of Disability Inventory (PEDI), at baseline (TO), 14 (T1) and 28 weeks (T2). **Results:** Developmental change between TO and T1 was similar in both groups; change scores in group A and B: GMFM-66 2.4 (SD±2.1) and 3.3 (SD±2.9) (p=0.412); PEDI mobility 8.4 (SD±6.6) and 3.5 (SD±9.2) (p=0.148), respectively. In two children muscle tone increased post-sWBV. 24 children received between 67 and 140 sWBV sessions, rate of completed sessions ranged from 48 to 100% and no dropouts were observed. **Conclusion:** A 14-week home-based sWBV intervention was feasible and safe in toddlers with CP, but was not associated with improvement in gross motor function.

Keywords: Cerebral Palsy, Whole Body Vibration, Early Intervention, Motor Development, Physical Therapy

Introduction

Cerebral palsy (CP) is characterized by an impaired development of motor control causing activity limitation[1]. Children with CP often receive physiotherapy to achieve maximum motor potential and prevent secondary conditions. A recent review has suggested that physiotherapy with training of daily activities is associated with improved function[2]. Another recent review and meta-analysis on whole body vibration (WBV) suggested that this therapy may be associated with improved function in children with CP as well[3]. However, this suggestion was based on only a few studies; therefore more research is needed in this field.

In previous work our group combined 6 months of home-based WBV training with intensive functional physiotherapy block-therapy. The results of the first 78 patients with CP (2-25 years) showed significant positive changes in bone mineral density, muscle force and mobility after training[4]. More recent results of 356 children with CP (mean age 8.9±4.4 years, GMFCS-Level I to IV) show a significant and clinically important increase in motor performance (GMFM-66) which was sustained after 6 months follow up after training[5]. Other studies have also shown positive effects of WBV on motor function in children and young adults with CP[6-11]. Based on these observations in older children with CP we are primar-

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Figure 1. Three different exercises on the side-alternating whole body vibration platform: A) Standing (if possible, alternately squatting and standing-up), B) Sitting and C) Four-point-position: knees on a stool in level of the WBV platform, hands on the platform supporting the trunk; if possible active trunk support und if possible play. Reproduced with permission of the parent.

ily interested in the safety, feasibility and secondarily in the effectiveness of WBV training in children with CP below the age of 2 years. To our knowledge WBV has never been investigated in this young age group before.

Evidence showed that early intervention and high intensities are more effective than later intervention with low intensities[12]. It has been suggested, that early intervention may improve cognitive development of young children, but has no or only minimal effect on motor development[13-15]. However, other evidence shows the neural effects of motor training[12], which gives hope for effective intervention possibilities, also at early age. Muscles and neuronal pathways are constantly changing in response to motor activity. As a consequence with the potential of both: positive and negative changes[16]. This shows the urgency for optimal strategies to promote and optimize function; but also to ensure that we are not allowing maladaptive changes through the lack of adequate intervention or delaying intervention[17]. It is still unknown which type of movement or motor tasks should be encouraged and when, and whether external devices are needed to encourage motor activities[12]. High intensities of therapy are very difficult to apply without a home-training program. We aim to stimulate the neuro-musculo-skeletal system through the reflex-based form of WBV training with high intensities of neuro-muscular responses. We expect the neuro-muscular stimulation to improve motor development compared to the development without additional WBV stimulation.

WBV is a reflex-based neuromuscular training on a vibrating platform. Previously, we applied side-alternating WBV (sWBV) which uses oscillatory motion around a pivot in the center of a platform and applies low forces to the body[18,19]. A typical sWBV session includes nine minutes of vibration (3x3 minutes) at a frequency of up to 30 Hz; in case of 20 Hz this implies 10.800 stimulatory impulses to the trained muscles in 9 minutes. This number of stimuli is similar to that of three hours of walking[20]. Therefore it is conceivable that sWBV is a feasible and time-effective training method. Acute and long-term effects of sWBV in adults consist of increased oxygen consumption, muscle temperature and skin blood flow (acute effects) and decrease of muscle and bone loss during immobilization, improved balance and decrease of falls (long-term effects)[20]. The exact working mechanism is still unknown; however "most authors hypothesize that vibrations stimulate muscle spindles and alpha-motoneurons, which initiate a muscle contraction"[20]. Effects on EMG-activity and a significant depression of the H-reflex have been shown in healthy adults[18]. Yet, sWBV studies in adults with neurological disorders, like stroke and Parkinson's disease, showed inconclusive results[20].

Suggested benefits of the addition of sWBV to traditional rehabilitation include: (A) faster gain of muscle function, since more stimulation cycles per unit of time may be applied than during typical activities (e.g., walking) and (B) practice in a safe condition, due to the controlled training position without the risk of falls[20]. Our first experiences indicated that sWBV might be a safe, feasible and potentially effective home-training program[5,21,22]. Previously, our group showed that the combination of six months of home-based sWBV-training with blocks of intensive functional physiotherapy in children with CP older than two years were associated with a significant[4] and clinically important increase in gross motor function that was maintained six months after training[5]. The recent review and meta-analysis by Saquetto et al. (2015) summarized six studies on WBV in children with CP and found improvements in gait speed, gross motor function dimension E and femur bone density. The meta-analysis showed nonsignificant differences in muscle strength and gross motor func-

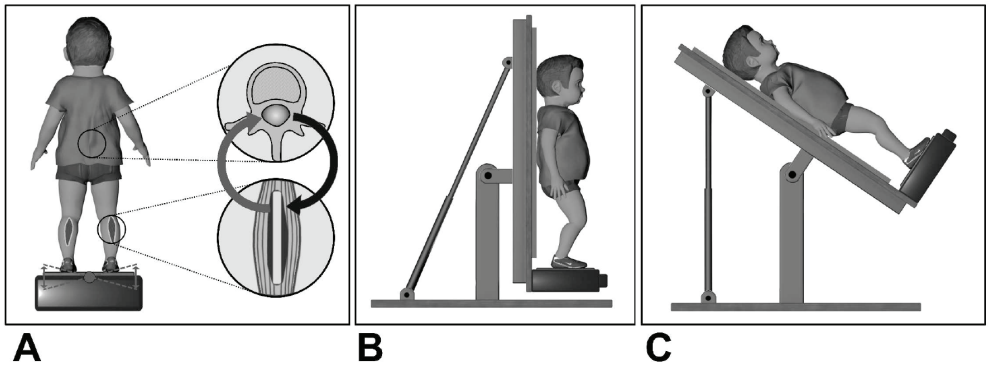


Figure 2. The side-alternating whole body vibration platform with tilt table. A) Mechanism of the reflex-based side-alternating SWBV; B) SWBV platform combined with the tilt-table in vertical position (90 degrees from the horizontal); C) The tilt table can be rotated from 90 to 0 degrees.

tion dimension D. No serious adverse events were reported according to this review. SWBV has not been investigated in children younger than two years.

The primary objective of this pilot-trial was to investigate the safety and feasibility of 14 weeks of home-based sWBV-training in children with CP between 12 and 24 months of age. A secondary objective was to explore the efficacy with the Gross Motor Function Measure (GMFM-66)[23] as change from week 0 to 14. We hypothesized that 14 weeks of regular physiotherapy with additional home-based sWBV-training would result in a larger change in GMFM-66 than 14 weeks of regular physiotherapy without sWBV; secondary parameters were the performance of functional tasks and cognitive development.

Materials and methods

The study has a prospective, evaluator-blinded, monocenter, randomized waiting-control design with follow-up. Participants were assessed three times: baseline (T0), 14 weeks (T1) and 28 weeks (T2). Group A received sWBV first (T0 to T1), with a sWBV-free follow-up (T1 to T2). Group B received sWBV between T1 and T2 (Figure 1). Throughout the study period participants received standard of care parallel to the WBV intervention. Standard of care includes all medication a child with CP would normally receive, including anticonvulsants and any therapeutic treatment. Standard of care for children with CP in Germany includes therapeutic treatment like physiotherapy (including all regimes like Bobath (NDT), Vojta, Petoe, pool therapy, hippotherapy etc.), Osteopathy, Motopaedie, Fruehfoerderung, orthotics and aids, occupational therapy and speech and language therapy. The children will receive WBV as an additional treatment so they will not miss out on a treatment, but receive an additional treatment.

Participants

Twenty-four participants were recruited through the Children's Hospital, University of Cologne (January 2012 to July 2013), Germany, or via cooperating centers within an 80 km area. The study was conducted in accordance with the principles of the Declaration of Helsinki and the ICH-GCP guidelines and was approved by the ethics committee of the University of Cologne (11-311). Written informed consent was obtained from the families before study-related procedures. The trial was registered at ClinicalTrials.gov (NCT 01491152).

Children with a diagnosis of CP or highly suspected to have CP were eligible. A second pediatric neurologist confirmed the child's neurological diagnosis[24]. Children younger than 18 months were included on the basis of clinical signs and lesions on brain imaging. All participants met the following inclusion criteria: (1) corrected age between 12 and 24 months and (2) Gross Motor Function Classification System (GMFCS) level II-IV (according to the definition for children <2 years[25]). Children were excluded if surgical interventions or medication changes that might affect motor function were scheduled during the study period; surgery, fractures or intracerebral hemorrhage had occurred in the three preceding months; acute inflammation of the musculoskeletal system, uncontrolled seizures, or additional severe congenital disorders, e.g., congenital heart defect, were present. Pregnant mothers were excluded from assisting training.

Randomization and blinding

The participants were randomized (using closed envelopes) into two groups with equal numbers. Block randomization (blocks of 2 and 4) was performed by SAS 9.1. Because of the nature of the intervention, participants could not be blinded to the treatment, but the physiotherapist completing the assessments was blinded to intervention.

Intervention

The intervention was a home-based, 14-week sWBV-training with a Galileo® system combined with a tilt table (Novotec Medical GmbH, Pforzheim, Germany). In previous studies the training period ranged from eight weeks to six months. Most studies had a six months intervention period[4,10,11,20,26-28], but Ahlborg et al. (2006) have shown positive effects already after eight weeks of training[27]. For our study we have chosen a 14-week intervention period (three months training (12 weeks) plus two weeks for the training period of the parents in the beginning). We learned from previous practice that a six months training period might be too long for children at this young age. In this study the children are even younger than in our previous studies and the diagnosis of CP has been recently established which is difficult for the families. The families may need time to adjust and cope with the diagnosis.

The sWBV platform consists of a motorized board that produces sinusoidal vibrations, alternately on the right and left side (Figure 2A). The table allowed tilting from 0 (supine) to 90 (full upright) degrees (Figure 2B-C). The frequency of vibration was either 12 Hz or 22 Hz. These frequencies were chosen based on the hypothesis that at 22 Hz reflex muscle contraction would be maximal achieving strengthening through muscle fatigue, and at 12 Hz the muscle response would be slower achieving neuromuscular coordination with central pattern effects (personal observation). The feet or hands were placed at equal distance from the center of the platform that correlated to a peak-to-peak displacement of a maximum of 2.5 mm; peak acceleration related to frequency being between 0.72 g (12 Hz) and 2.43 g (22 Hz). The intensity of 22 Hz in standing was not reduced.

SWBV-training consisted of ten 9-minute sWBV sessions per week. 3x3 minutes is the intensity our group[4,11,26] and other groups[10,20] used, and no side effects or complains have been reported so far. On the basis of previous studies[4,26] and our experience we suggest WBV training twice a day. From clinical practice with the families we derived our suggestion to train ten times per week to give families the opportunity to select the training periods individually: either training twice per day during the week or once per day during the week and twice on weekend days (incl. Friday).

Each sWBV session involved three exercises, each lasting three minutes: (A) standing still or alternately squatting and standing up – depending on the child's capacities, (B) sitting on the platform and (C) "four point position" (hands on the platform) (Figure 1). To increase the variation in stimuli provided, the vibration frequencies of 12 Hz and 22 Hz alternated between exercises. This meant for instance for session one: exercise A at 12 Hz, B at 22 Hz and C at 12 Hz; session two: exercise A at 22 Hz, B at 12 Hz and C at 22 Hz; session three: exercise A at 12 Hz, B at 22 Hz and C at 12 Hz, etc.

For the "standing" exercise (Figure 1A), the child was positioned on the tilt table with his/her feet on the vibration platform. Slipping of feet was minimized by manual stabilization and orthoses when needed. There was no standardization on the footwear, because the individual needs were too different. If possible the children trained without shoes, but with socks. The child was initially supported with a strap around the trunk. If the child was not able to stand, training started with the table at a minimum angle of 40 degrees (Figure 2C). Ten degrees were added each week until full upright position (90 degrees, Figure 2B) was achieved in week seven. If the child initially was able to stand fully upright, the sessions started in this position. It was very important that the knees were bent throughout the standing exercise. All other exercises (Figure 1B and C) were performed with the platform at 90 degrees.

All parents received the study's training manual, a training log and three introductory sessions (within the first two weeks, 45 minutes each) provided by the same experienced physiotherapist at home (including information on the device, exercises and general information). The home-based training started after the first introductory session and was monitored during the following two introductory sessions. An additional home visit for surveillance occurred after eight weeks.

Outcome measurements

Each study visit included a physical examination by a pediatric neurologist and assessment by an experienced pediatric physiotherapist. Training adherence was calculated as the number of completed training sessions. Safety was assessed by parents who recorded the number of adverse events (AE) and serious adverse events (SAE) in the training log, by parental report during the sWBV-free periods, and by systematic evaluation at each study visit. AEs and SAEs were defined according to ICH GCP guidelines.

The primary outcome measure for motor function was the Gross Motor Function Measure (GMFM-66). The GMFM is a widely used measure of gross motor function validated for children with CP[23,29]. Function in daily life was assessed with the Functional Skills Scale (FSS) of the German version of the Pediatric Evaluation of Disability Inventory (PEDI-G) in the self-care and mobility domains[30]. The PEDI has shown to be reliable and responsive over time[31]. The PEDI is validated as a structured interview with the caregiver[30]. In our study the parents filled in the PEDI as a questionnaire while the child's GMFM testing was carried out[32]. Cognitive development was assessed with the German Bayley-II Mental Scale[33], which previously showed an effect of early intervention[14]. Raw scores were converted to the Mental Developmental Index (MDI). The MDI assesses social and language skills, memory, problem solving, discrimination and classification.

Statistical analysis

Feasibility of sWBV was analyzed for all 24 patients in one group. The intention-to-treat (ITT) population included all randomized patients with GMFM-66 measured at T0 and T1. The per protocol (PP) set was defined as having completed at least 70% of the possible training sessions and not having skipped more than two successive weeks (Figure 4). All results refer to the ITT population if not stated otherwise,

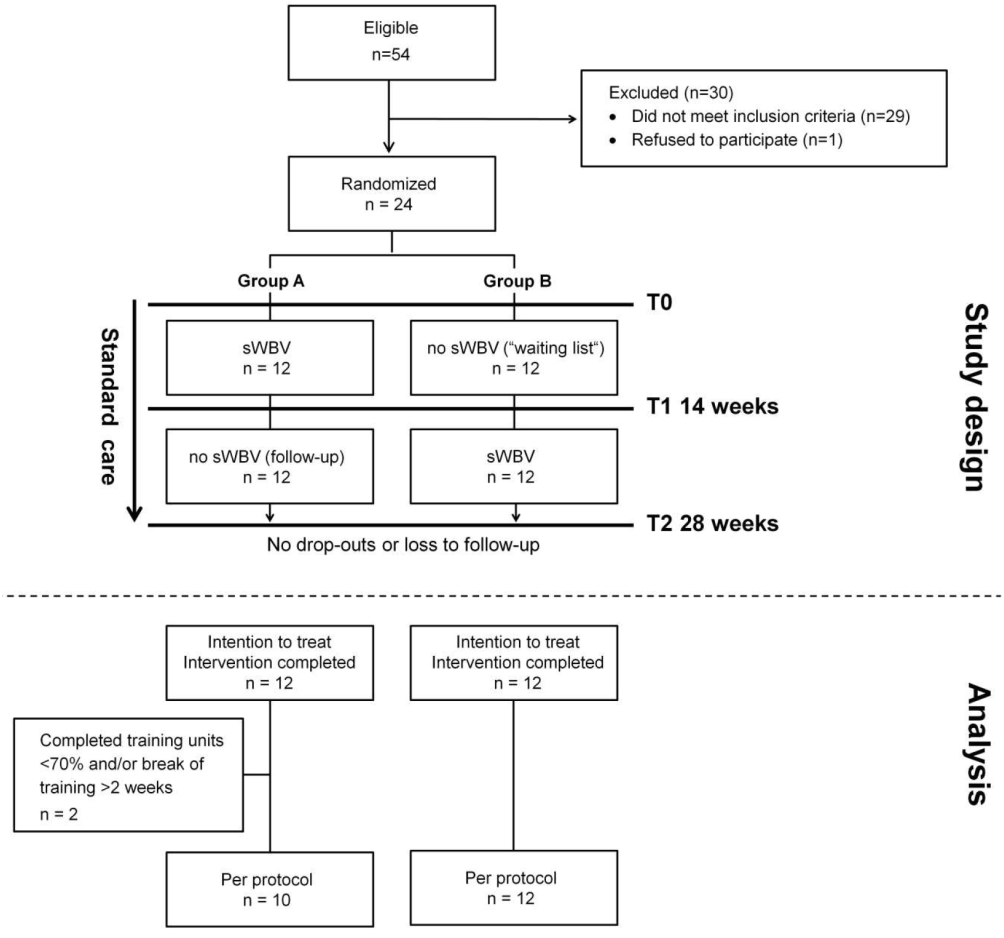
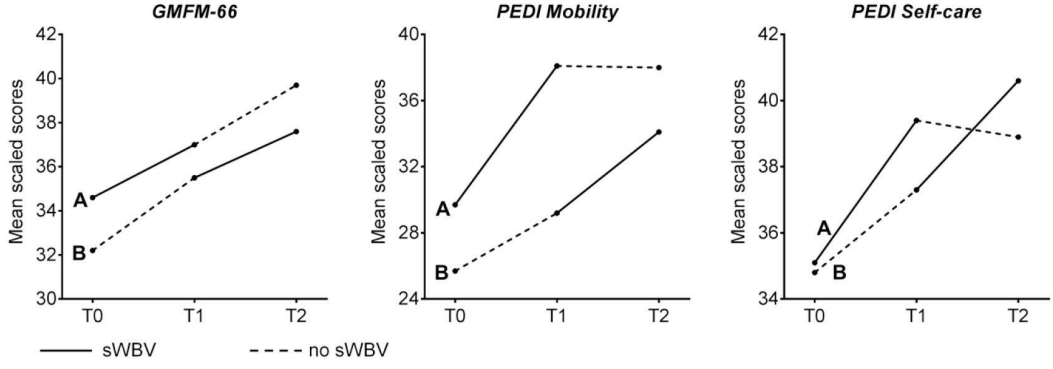


Figure 3. Flow diagram of children eligible and included in the analyses.



	Baseline T0		14 weeks T1		28 weeks T2	
	Group A	Group B	Group A	Group B	Group A	Group B
GMFM-66 Score	34.6 (11.9)	32.2 (9.2)	37.0 (12.3)	35.5 (9.0)	39.7 (13.9)	37.6 (8.9)
PEDI Mobility FSS	29.7 (15.9)	25.7 (10.3)	38,1 (17.1)	29.2 (12.4)	38.0 (18.0)	34.1 (12.4)
PEDI Self-care FSS	35.1 (8.2)	34.8 (8.1)	39.4 (8.7)	37.3 (9.5)	38.9 (8.8)	40.6 (7.4)

Figure 4. Development of GMFM-66 and PEDI scores in the two groups. *TO= baseline, T1= after 14 weeks, and T2= after 28 weeks. FSS: Functional Skill Scale. None of the changes were statistically significant. All values mean and (SD±).*

Table 1. Clinical characteristics at baseline and details of intervention in the two study groups.

	Total n=24	Group A n=12	Group B n=12
Male (n)	13	6	7
Female (n)	11	6	5
Age at baseline, mean, (SD±)	19.0 (3.1)	18.6 (3.2)	19.4 (3.2)
<18mo (n)	9	6	3
≥18mo (n)	15	6	9
Height [cm], mean, (SD±)	82.2 (4.3)	81.3 (4.5)	83.2 (4.0)
Weight [kg], mean, (SD±)	10.4 (1.4)	10.3 (1.7)	10.4 (1.0)
GMFCS level (n)			
II	11	6	5
III	4	2	2
IV	9	4	5
Motor milestones (best) (n)			
Rolling or less	7	3	4
Crawling	6	3	3
Sitting	4	0	4
Pull to stand or better	7	6	1
Bayley II	73.9 (16.2)	74.7 (19.7)	73.0 (12.8)
Max. training sessions: 140	**N**	**Completed sessions Mean (SD±)**	**Sessions in vertical position Mean (SD±)**
Total	24	79 % (13)	100 % (32)
Group A	12	83 % (14)	99 % (41)
Group B	12	76 % (12)	101 % (22)
GMFCS level II	11	83 % (13)	111 % (20)
GMFCS level III	4	83 % (6)	108 % (14)
GMFCS level IV	9	74 % (15)	84 % (44)

mo = months; GMFCS = Gross Motor Function Classification System.

since the PP analysis mostly confirmed the ITT results. PEDI values <10 and Bayley-II values <50 were replaced by "9" and "49" respectively for analysis. For subgroup analysis training frequency was categorized as <100 / 100-119 / ≥120 completed sessions.

Statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA). The change from T0 to T1 was compared between study groups and both treatment periods were compared (early vs. later start of training). Metric variables were evaluated by t-test or Mann-Whitney-U-test, depending on distribution, frequencies by Fisher Exact test. ANOVA and ANCOVA were used for subgroup analyses, including treatment. Two-sided p values <.05 were considered statistically significant.

Results

Twenty-four patients were included and randomized, twelve in each group. At baseline the children aged 14 to 24 months (mean 19 months). The clinical characteristics did not differ significantly at baseline (Table 1).

Feasibility

The 24 children received between 67 and 140 sWBV sessions. The rate of completed sessions ranged from 48 to 100% (Table 1). Two children of group A did not meet the criteria for per protocol analysis (Figure 4) since they both completed less than 70% of the planned sWBV sessions due to family holidays and death of a relative. Two children were not able to cope with the full 3 minutes of exercises A and C. The first was a group A girl (GMFCS level IV); she had to reduce the time to one minute after 6 weeks until the end of study, because she could not hold the position. The second was a group B boy, who started with a shorter time but advanced to three minutes after three weeks.

Twenty children started at 90 degrees (full upright position). Two children started at 80 and 70 degrees respectively (both progressing to 90 degrees after three weeks); two started at 50 degrees: one progressing to 90 degrees by week 8 and one (level IV) decreasing to 20 to 30 degrees by week 4 until the end of the study because it was too exhausting for the parents to hold the child. These two children were the same mentioned above with limited training time.

Table 2. Adverse and serious adverse events.

Child	Gr.	Study period	AE No.	Description	SAE	Description	Outcome
01	A	before start sWBV	1	Bronchitis	No	-	-
08	A	sWBV	1	Dehydration due to infection with increased temperature	Yes	Inpatient treatment	resolved without sequelae
13	A	sWBV	1	Otitis media, gastroenteritis, seizure (known epilepsy)	Yes	Inpatient treatment	resolved without sequelae
		sWBV	2	Infection with increased temperature	No	-	-
16	A	Follow-up (no sWBV)	1	Increased muscle tone (parent report)	No	-	-
20	A	Follow-up (no sWBV)	1	Increased muscle tone (parent report)	No	-	-
		Follow-up (no sWBV)	2	Decreased active movement (parent report)	No	-	-
23	A	sWBV	1	Otitis media	Yes	Inpatient treatment	resolved without sequelae
02	B	"waiting list" (no WBV)	1	Increased temperature	No	-	-
19	B	"waiting list" (no WBV)	1	Gastroenteritis	Yes	Inpatient treatment	resolved without sequelae
	B	"waiting list" (no WBV)	2	Rota Virus infection	Yes	Inpatient treatment	resolved without sequelae
	B	sWBV	3	Suspicion of Bronchopneumonia	Yes	Inpatient treatment	resolved without sequelae
24	B	sWBV	1	Pneumonia with increased temperature	No	-	-

Gr. = group

Safety

In total, 13 adverse events were reported in the study period (Table 2). Ten of them consisted of common childhood illnesses and three were related to the musculo-skeletal system. Referring to the events reported in Table 2 the following can be summarized:

a) sWBV (active training, group A and B): no adverse events.
b) No sWBV (follow-up, group A): three adverse events in two children associated with increased muscle tone were reported by spontaneous parent account. One mother reported increased muscle tone (AE1) with decreased active movement (AE2) and another mother reported increased muscle tone (AE3) (both compared to the active sWBV period). Both children were functioning at GMFCS level IV.

Six serious adverse events have been reported in the study period: three in group A, and three in group B. All serious adverse events were caused by common childhood illnesses with hospitalizations, were not related to the study, and were resolved without sequelae.

Efficacy

Between the baseline assessments at TO and the first evaluation at T1, both groups improved in GMFM-66 scores. The difference between T1 and TO was 2.4 (SD±2.1) points for group A and 3.3 (SD±2.9) points for group B (Figure 4) with no statistically significant difference between the groups (p=0.412). Also the comparison between the early and late start of sWBV did not reveal statistically significant differences (p=0.767).

The PEDI-G mobility change score (TO to T1) in group A was 8.4 (SD±6.6), that in group B 3.5 (SD±9.2). Between groups there was no significant difference (p=0.148). Likewise, the change score in the self-care domain was 4.3 points (SD±3.1) in group A and 2.5 (SD±3.6) in group B (p=0.208). In the second period, improvements in the PEDI-G scores in both groups were also similar (Figure 4). Here also, improvement of the early sWBV group did not differ from that of the late sWBV group.

The Bayley-II scores did not change significantly in both groups in both periods.

Sub-group analysis

Sub-group analyses were based on GMFCS level, Bayley-II scores at baseline and training frequency (number of completed sWBV sessions). The three covariates did not have a statistically significant effect on the results of the ITT analy-

sis. However, in the PP-analysis two significant effects were found. First, the ANCOVA of the PEDI self-care change from TO to T1 revealed a significant effect of the Bayley-II score at baseline, with lower MDI-scores being associated with worse improvement of PEDI self-care (p=0.0104). Second, the PEDI self-care change in group A showed also a statistically significant positive effect of training frequency (p=0.0434).

Discussion

In this pilot study, we found that a 14-week home-based sWBV-training was feasible for children with CP aged 12-24 months. In general, sWBV was well tolerated and treatment compliance was high.

Regarding safety, no serious adverse events during sWBV-training were observed, nor did children regress in motor development. In two of nine children functioning at GMFCS level IV an increase in muscle tone in the post-sWBV period was spontaneously reported by parents. However this has not been clinically verified. It could be hypothesized that especially children with severe impairments, including high muscle tone, may be sensitive to the effects of sWBV. The current clinical observation deserves further systematic analysis.

With regard to efficacy, the pilot study was not able to demonstrate statistically significant differences in developmental change between intervention with and without sWBV and between early and late onset of sWBV. Both groups showed clinically relevant improvements in the GMFM-66: 2.4 points in group A and 3.3 points in group B[29]. Possibly, group B developed better in GMFM-66 scores due to a baseline difference in development: six children in group A were at least able to pull to stand compared to one child in group B. Accordingly group B may have had a better "motor development potential". However, seven children achieved this milestone in group B at T1. This finding underlines the notion that variability in spontaneous development is a major scientific and social challenge because large sample sizes are needed to study this population with reliable results.

The absence of significant differences between the groups with and without sWBV could also be due to the fact that training was not individualized. It is conceivable that young children benefit in particular from sWBV if it is part and parcel of an individualized training tailored to the individual's motor capacities.

The changes in GMFM-66 scores in the current study are similar to those reported in a previous study in older children (2 to 25 years). In the latter study six months of home-based sWBV combined with intensive blocks of functional training was associated with a change in GMFM-66 of 3.4 points[5]. As the current study reached the effect in half of the time, this may imply an effect of age – the younger nervous system being more plastic than the older – or an effect of dosage. The subgroup analysis in which a minor effect of frequency of training on the PEDI self-care scores was found supports the latter suggestion. This idea is also in line with emerging evidence that dosage, i.e., treatment amount and frequency, is an important key to the success of intervention in children with CP[34].

An interesting result was observed in the PEDI results: the improvement in group A during training diminished during follow-up. This was not the case for the GMFM-66 which was administered by a physiotherapist blinded to treatment allocation. The PEDI was a parent report and parents were involved in training. Given that motivation to participate in the study was high, this might have influenced the parents' perceptions of their child's abilities.

We expect younger children with CP to show more progress in the GMFM than older children due to their natural development[35]. Most of the studies published on intervention in CP include older children. Recently more and more data on early intervention is published: One study investigated a "new mobility training" in five children (12-36 months of age). They used the GMFM-66 in a single-subject design with a 6-week training period; the results are difficult to compare because of the very small sample[36]. Law et al. (2011) conducted a randomized controlled trial on child- vs. context-focused intervention for young children with CP (n=128, mean 3 years 6 months). They did not find a difference between groups and had significant results for PEDI self-care und mobility. Their change scores were smaller compared to our change scores, but the results were statistically significant, whereas ours were not. In some of the PEDI domains they showed the same decline in follow-up like our results[37]. Duncan et al. (2012) conducted another RCT in young children with CP (n=75, 12 to 72 months of age) evaluating intensive 12 week rehabilitation with and without acupuncture. They did not find significant differences. Again the results are very similar to our results with PEDI scores between 1.1 and 6.9 points change scores and GMFM-66 change scores between 2.1 and 4.3 points[38].

The strength of the study is that it for the first time addressed the feasibility, safety and potential efficacy of home-based sWBV in children with CP below the age of two years. In addition, it may be regarded another strength that the same masked assessor carried out the GMFM-66 evaluations. Yet, the study also has a number of limitations: the study has a small sample size which hampers generalization and interpretation, and the duration of intervention was relatively short. Also the fact that the PEDI was administered as a questionnaire and not as an interview performed by a masked assessor may be regarded a limitation.

In conclusion we found that a 14-week home-based sWBV-training was feasible in children with CP aged 12 to 24 months. In general, sWBV was well tolerated and treatment compliance was high. SWBV was not associated with short-term effects on gross motor function and function in daily life as measured with GMFM-66 and PEDI. Our data suggest that future studies should address the effect of sWBV on muscle tone, especially in children with CP functioning at GMFCS levels IV and V, the effect of dosage and a higher degree of individualized therapy.

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